



Complaint Handling and Medical Device Reporting (MDRs)

**FDA Small Business
Regulatory Education for Industry (REdI)**
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Andrew Xiao

Consumer Safety Officer, Postmarket and Consumer Branch
Division of Small Manufacturers, International and Consumer Assistance
Office of Communication and Education
Center for Devices and Radiological Health
U.S. Food and Drug Administration



Discussion Overview

- 21 CFR 820.198: Quality System Regulation – Complaint Files
- 21 CFR 803: Medical Device Reporting (MDR) Regulation



Complaint Files

Quality System Regulation 21 CFR 820.198



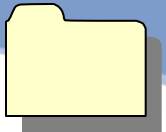
Complaint Files (21 CFR 820.198)

- **A Complaint is:**

Any written, electronic, or oral communication that alleges deficiencies related to the identity, quality, durability, reliability, safety, effectiveness, or performance of a device after it is released for distribution.

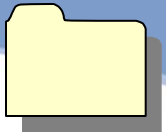
- **All manufacturers must:**

- Maintain complaint files.
- Designate a formal complaint handling unit.
- Establish and maintain procedures for receiving, reviewing, and evaluating complaints.



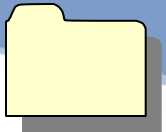
Complaint Files Continued

- **Procedures must ensure that:**
 - All complaints are processed in a uniform and timely manner.
 - Oral complaints are documented upon receipt.
 - Review and evaluate all complaints to determine whether an investigation is necessary.
 - When no investigation is made, manufacturers must maintain a record that includes the reason no investigation was made and name of the individual responsible for the decision.



Complaint Files Continued

- **Procedures must ensure that:**
 - Complaints are evaluated to determine whether the complaint represents a reportable event, also known as a Medical Device Report (MDR), according to 21 CFR 803.
 - Complaints representing an MDR shall be promptly reviewed, evaluated, and investigated.
 - Such complaints should be maintained in a separate portion of the complaint file or otherwise clearly identified.



Complaint Files Continued

- **Records of investigation** will include determination of:
 - Identifiers related to the device and reported event
 - If MDR reportable:
 - Whether the device failed to meet specifications
 - Whether the device was being used for treatment or diagnosis
 - If applicable, the relationship of the device to the reported event
- Complaint files need to be reasonably accessible to the manufacturer



Mandatory Medical Device Reporting

Medical Device Reporting Regulation 21 CFR 803



Mandatory Medical Device Reporting (21 CFR 803)

- The Federal Food, Drug, and Cosmetic Act, Section 519 – Records and Reports on Devices – grants the FDA authority to require mandatory medical device reports from:
 - Manufacturers
 - Importers
 - Device User Facilities
- A report does NOT constitute an admission that the device or manufacturer employee caused or contributed to the reportable event



Key Terms

- **“Become Aware”:**

An employee or personnel of the entity required to report has acquired information that reasonably suggests a reportable adverse event has occurred.

- **“Caused or Contributed”:**

- Death or serious injury was or may have been attributed to a medical device, or
- A medical device was or may have been a factor in a death or serious injury, including events resulting from failure, malfunction, improper or inadequate design, manufacturing (problems), labeling (problems), or use error.



Key Terms Continued

- **Serious Injury:**

A reportable serious injury is an injury or illness that is:

- Life-threatening, or
- Results in permanent* impairment of a body function or permanent* damage to a body structure, or
- Necessitates medical or surgical intervention to preclude permanent* impairment of a body function or permanent damage to a body structure.

*Permanent means irreversible impairment or damage to a body structure or function, excluding trivial impairment or damage.

- **Malfunction:**

The failure of a device to meet its performance specifications or otherwise perform as intended.

- **Initial Reports (30 Day Reports):**

A manufacturer must submit a report within 30 calendar days of becoming aware of an MDR Reportable Event (see slide 13).



Key Terms Continued

- **5 Day Reports:**

A manufacturer must submit a report within 5 working days of becoming aware of:

- A MDR reportable event that necessitates remedial action to prevent unreasonable risk of substantial harm to the public health
- A MDR reportable event for which the FDA has made a written request for 5-day reports

- **Supplemental Reports:**

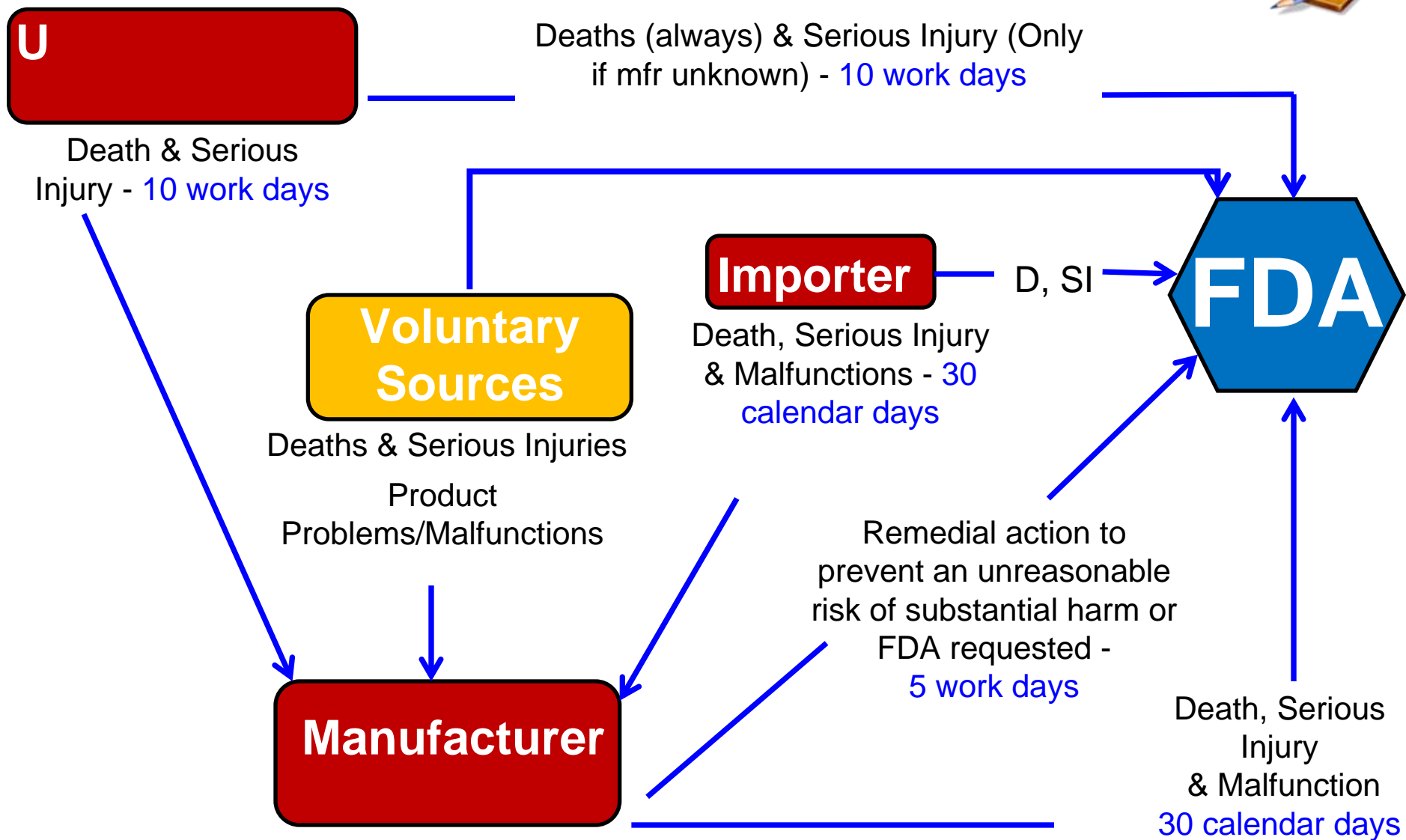
- Supplemental reports must be submitted:
 - Whenever a manufacturer becomes aware of information that was not provided in the initial MDR
 - Within 30 calendar days from receipt of the additional information
- Indicate on 3500A that report is supplement, Provide Manufacturer Report Number from the initial MDR, and Only fill in the blocks on the 3500A that have changed



What is a MDR Reportable Event?

- **A MDR Reportable Event is:**

- 1) User Facility: death or serious injury
- 2) An event that manufacturers or importers become aware of that reasonably suggests that one of their marketed devices:
 - May have caused or contributed to a death or serious injury, or
 - Had malfunctioned and ... would be likely to cause or contribute to a death or serious injury if the malfunction were to recur.





Who is a Manufacturer?

- Any person who manufactures, prepares, propagates, compounds, assembles, or processes a device by chemical, physical, biological, or other procedure.
- This includes:
 - Domestic Manufacturers
 - Repackagers
 - Relabelers
 - Contract Manufacturers
 - Specification Developers
 - Foreign Manufacturers



When do Reporting Requirements Apply to Manufacturers?

- When any employee becomes aware of information from any source that reasonably suggests that a device it markets:
 - Has or may have caused or contributed to a death or serious injury or experienced a reportable malfunction
- When FDA requests 5-day reports
- When an employee with management or supervisory responsibilities or with duties to collect and report adverse events becomes aware that a reportable event necessitates remedial action to prevent an unreasonable risk of substantial harm to the public health (5 day report)



Mandatory Requirements for Manufacturers

- Manufacturers are required to:
 - **Investigate each event** to determine the cause of the event (21 CFR Part 803.50(b); if unable to determine cause, provide explanation and steps taken to obtain the information.
 - Provide all **information reasonably known** about the event to FDA, including (21 CFR Part 803.52):
 - Any information that can be obtained by contacting the reporter
 - Any information in your possession
 - Any information that can be obtained by analysis, testing or other evaluation



Mandatory Requirements for Manufacturers Continued

- Manufacturers are required to:
 - Submit **initial reports** of death, serious injury and malfunction within 30 calendar days (21 CFR Part 803.50);
 - Submit **5-day reports** within 5 work days (21 CFR Part 803.53) [Work Day = Monday -Friday, excluding Federal holidays];
 - Submit **supplemental reports** within 30 calendar days of receipt of new/changed information (21 CFR Part 803.56);
 - Have **MDR procedures** (21 CFR Part 803.17);
 - Establish and maintain **MDR event files** (21 CFR Part 803.18);
 - Manufacturers are required to report information listed in 21 CFR 803.52 – corresponds generally to **FDA Form 3500A**.



When Would Manufacturers Not Need to Report

- An MDR is not required when:
 - A manufacturer receives erroneous information and a device-related event did not occur.
 - A manufacturer determines that the device was manufactured or imported by another firm.
 - When a manufacturer receives this type of report, it must forward the report to the FDA with a cover letter.



Exemptions

Part 803.19 - Exemptions, Variances or Alternative Forms of Reporting

FDA may exempt a manufacturer from some or all of the reporting requirements. Here are some examples:

- **Alternative Summary Reporting (ASR):** a subset of the information required for FDA Form 3500A.
- **Total exemption** for specific device and/ or patient related events.
- **Remedial Action Exemption (RAE)** for recalled products covered by 21 CFR Part 806 (Corrections and Removals).
- **Variances** may include extending the reporting timeframes under certain circumstances or using the registration number of the manufacturers reporting site rather than the manufacturing site for the Manufacturer Report Number.



MDR Event Files

Manufacturers must:

- Establish and maintain MDR event files. Files may be written or electronic and may refer to other information/files (i.e. medical records, patient files, engineering reports).
- Permit FDA access to files, to copy and verify the MDR records.
- Retain MDR event files for:
 - 2 years from the date of the adverse event; or
 - A period of time equivalent to the expected life of the device (whichever is greater)
 - If the device is no longer distributed, you still must maintain MDR event files for the time periods described.



Event Codes for 3500A

The FDA worked with National Cancer Institute (NCI) terminology experts to:

- Reduce duplication and redundancy in current coding.
- Create a hierarchy that allows grouping.
- Store and maintain the new coding system in the NCI Thesaurus.
(Available on the public website/can be downloaded into applications).
- Improve the detection of device safety problems.

**Users can request new codes at:

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/EventProblemCodes/default.htm>



Reference: Address for Mandatory Reporting

**FDA
Center for Devices and Radiological Health
Medical Device Reporting
P. O. Box 3002
Rockville, MD 20847-3002**

- *Please note the topic on the envelope: Manufacturer or Importer Initial Report, 5-day, or Supplemental Report*

Voluntary Reporting Program for Patients, Consumers, & Healthcare Professionals

- Four ways to inform FDA:
 - Telephone: 1-800-FDA-1088
 - Online report form 3500
(<https://www.accessdata.fda.gov/scripts/medwatch/medwatch-online.htm>)
 - Download or print the FDA Form 3500 or FDA Form 3500B and then fax or mail to specified fax number or mail box address in instruction sections for each form.
 - MedWatcher Mobile Application



FDA 3500 Series Forms

- FDA Form 3500 is the general voluntary reporting form for healthcare professionals, consumers, and patients.
- FDA Form 3500**A** is the mandatory reporting form for manufacturers, importers, and user facilities.
- FDA Form 3500**B** is the voluntary reporting form that was designed specifically for consumers. While its purpose is the same as FDA Form 3500, the 3500B form is the more "consumer-friendly version" of the FDA Form 3500.



MedWatcher

Mobile Application

- MedWatcher is NOT intended to fulfill mandatory reporting requirements (manufacturers, importers, etc).
- MedWatcher is a mobile application that allows individuals to submit voluntary reports of serious medical device problems to the FDA using a smart phone or tablet, including uploaded photographs.
- Users can also choose to automatically receive MedWatch Safety alerts, FDA safety communications, recall information, relevant articles and other information on specific medical products of interest.



How Does the FDA Use MDRs

- Event reports are analyzed by FDA staff including health care clinicians, engineers and scientists.
- Follow-up actions that FDA may take:
 - Request for additional information
 - Conduct an investigation of the event
 - Conduct an inspection at the manufacturer, importer or user facility
 - Contact the manufacturer about a recall
 - Issue a public health advisory/safety alert



FDA Product Evaluation Analysts

Analysts analyze & review MDRs accounting for the following:

Is the event...

- A known complication of the device
- An inherent risk of the device
- Related to human factors
- A result of off-label use

Additionally, analysts consider...

- Is the device labeling adequate?
- Is there a design change or is one needed?



Publically Available MAUDE

- MAUDE = Manufacturer and User Facility Device Experience Reports of adverse events involving medical devices.
 - Voluntary reports since June 1993
 - User Facility reports since 1991
 - Distributor reports since 1993
 - Manufacturer reports since August 1996
 - May not include reports made according to exemptions, variances or alternative reporting requirements.
- FOI releasable event and manufacturer text narratives are provided in the database.
- Information is updated once a month (usually on the 6th of the month).
- There may be more than one report for an event.
- Both web search and downloadable files are available.

Resource Websites

- ◆ Office of Surveillance and Biometrics Guidance Documents:
<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070275.htm>
- ◆ Draft Guidance Document: Medical Device Reporting for Manufacturers:
<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm359130.htm>
- ◆ Code of Federal Regulations 21 CFR Part 803:
<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?CFRPart=803&showFR=1>
- ◆ Medical Device Reporting (MDR):
<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm>
- ◆ Alternative Summary Reporting:
<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm072029.htm>
- ◆ Remedial Action Exemption:
<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm071354.htm>

Resource Websites

- ◆ FDA 3500 Series Forms and instructions:
<http://www.fda.gov/Safety/MedWatch/HowToReport/DownloadForms/default.htm>
- ◆ MedWatcher Mobile Application:
<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/FormsandInstructions/ucm348271.htm>
- ◆ How to Report a Medical Device Problem:
<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/FormsandInstructions/default.htm>
- ◆ Web Search MAUDE Database (NOTE: Public adverse event information is redacted and may take up to 30 days to be inputted.):
<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/search.CFM>
- ◆ Downloadable MAUDE Data:
<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/ReportingAdverseEvents/ucm127891.htm>

Providing Industry Education and Assistance – CDRH Resources

- **CDRH Learn – Online Regulatory Training Tool**
 - Over 50 Medical device and Radiological Health modules
 - Video and PowerPoint presentations available 24/7
 - Certificate of completion upon passing post-tests
 - Many modules are translated into Chinese and Spanish
 - <http://www.fda.gov/Training/CDRHLearn/>
- **Device Advice – Online Regulatory Information**
 - Searchable by topic
 - <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/>

Providing Industry Education and Assistance – CDRH Resources

- **General questions: DSMICA**

Email: dsmica@fda.hhs.gov

Phone: (800) 638-2041
(301) 796-7100

- **Interpretations on MDR policy: MDR Policy Group**

Phone: (301) 796-6670 (voice)

Email: MDRPolicy@fda.hhs.gov



Discussion

